

SEP 15 2011

K112360
MAQUET
GETINGE GROUP

510 (K) Summary [as required by 21 CFR 807.92(c)]

SUBMITTER: MAQUET Cardiopulmonary AG
Hechinger Strasse 38
72145 Hirrlingen, Germany

CONTACT PERSON: Katrin Schwenkglenks
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DATE PREPARED: August 12, 2011

DEVICE TRADE NAMES: QUADROX-i Microporous Membrane Oxygenators, QUADROX-iD Diffusion Membrane Oxygenators, QUADROX-iR, HLS modules and PLEGIOX Cardioplegia Heat Exchanger

COMMON/USUAL NAME oxygenator with and without integrated arterial filter, with and without integrated centrifugal pump, cardioplegia heat exchanger

CLASSIFICATION NAME oxygenator, cardiopulmonary bypass, heat exchanger, cardiopulmonary bypass, filter, blood cardiopulmonary bypass, arterial line, non-roller type cardiopulmonary bypass.

LEGALLY MARKETED MAQUET PREDICATE DEVICES

QUADROX-i Adult Microporous Membrane Oxygenators K082117 & K090511, QUADROX-i Small Adult Microporous Membrane Oxygenators K090689 & K093522, QUADROX-i Pediatric Microporous Membrane Oxygenator K103191, QUADROX-i Neonatal Microporous Membrane Oxygenator K102464, QUADROX-iD Adult Diffusion Membrane Oxygenator K101153, QUADROX-iD Pediatric Diffusion Membrane Oxygenator K100278, QUADROX-iR Adult K102627, QUADROX-iR Small Adult K102627, HLS modules K102627 and PLEGIOX Cardioplegia Heat Exchanger K090555.

DEVICE DESCRIPTION / INDICATIONS FOR USE STATEMENT

QUADROX-i Adult Microporous Membrane Oxygenator with and without integrated Arterial Filter

The membrane oxygenator Quadrox-i Adult is intended for the use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. Within the specified flow rate range, the device oxygenates the blood, eliminates carbon dioxide and regulates blood temperature. The Quadrox-i Adult (HMO 71000) version with integrated arterial filter also filters out air bubbles and particles larger than 40 µm. The device's utilization period is limited to six hours.

Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

QUADROX-i Small Adult Microporous Membrane Oxygenator with and without integrated Arterial Filter

The membrane oxygenator QUADROX-i Small Adult is intended for the use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. The blood flow rate is defined from 0.5 – 5 L/min. Within the specified flow rate range, the device oxygenates the blood, eliminates carbon dioxide and regulates blood temperature. The QUADROX-i Small Adult (HMO 51000) version with integrated arterial filter also filters out air bubbles and particles larger than 40 µm. The device's utilization period is limited to six hours.

Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

QUADROX-i Pediatric Microporous Membrane Oxygenator with and without integrated Arterial Filter

The membrane oxygenator QUADROX-i Pediatric is intended for use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. It is designed for a blood flow rate of 0.2 – 2.8 l/min and is intended for the treatment of pediatric patients. Within the specified flow rate range, the device oxygenates the blood, removes carbon dioxide and regulates the blood temperature.

The QUADROX-i Pediatric (HMO 31000) model with integrated arterial filter also filters air bubbles and particles larger than 33 µm.

The utilization period of this device is restricted to six hours.

Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

QUADROX-i Neonatal Microporous Membrane Oxygenator with and without integrated Arterial Filter

The membrane oxygenator QUADROX-i Neonatal is intended for use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. It is designed for a blood flow rate of 0.2 – 1.5 l/min and is intended for the treatment of pediatric patients.

Within the specified flow rate range, the device oxygenates the blood, removes carbon dioxide and regulates the blood temperature.

The QUADROX-i Neonatal (HMO 11000) model with integrated arterial filter also filters air bubbles and particles larger than 33 µm.

The utilization period of this device is restricted to six hours.

Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

QUADROX-iD Adult Diffusion Membrane Oxygenator

The QUADROX-iD Adult Diffusion Membrane Oxygenator is intended for use in an extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. Within the specified flow rate range, the device oxygenates the blood, removes carbon dioxide from the blood and regulates the blood temperature. The application duration is limited to 6 hours.

Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

QUADROX-iD Pediatric Diffusion Membrane Oxygenator

The Diffusion Membrane Oxygenator QUADROX-iD Pediatric is intended for use in an extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. The oxygenator is designed for a blood flow rate of 0.2 – 2.8 l/min and is intended for the treatment of pediatric patients. Within the specified flow rate range, the device oxygenates the blood, removes carbon dioxide and regulates the blood temperature.

The utilization period for this device is restricted to six hours.

Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

The HLS modules Advanced and the QUADROX-iR are disposables which are part of the CARDIOHELP System, the indications for use is as follows:

The CARDIOHELP System is a blood oxygenation and carbon dioxide removal system used to pump blood through the extracorporeal bypass circuit for circulatory and/or pulmonary support during procedures requiring cardiopulmonary bypass (for periods up to six hours). It is also intended to provide circulatory and/or pulmonary support during procedures not requiring cardiopulmonary bypass (for periods up to six hours).

The CARDIOHELP System in configuration with the HLS/HIT Set Advanced is intended to be used within the hospital environment and outside the hospital environment (for periods up to six hours), e.g. for intra- and inter-hospital transport.

The CARDIOHELP System in configuration with the QUADROX-iR is intended to be used in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery (for periods for up to six hours).

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The modified devices as mentioned above are identical to the originally cleared devices, with the only exception that the modified devices come with a modified warp thread. Besides this difference the devices are the same in design, intended use, method of operation, components, packaging, and fundamental scientific technology.

RISK ANALYSIS

The risk analysis method used to assess the impact of the modification was done according to the logic of a Failure Modes and Effects Analysis (FMEA). The design verification tests were performed as a result of this risk analysis assessment.

All possible risks for the user and the patient related to the design change (material change) have been assessed by evaluation or testing according to the risk analysis. The following hazards have been addressed: general hazards, functional hazards and manufacturing hazards.

The evaluation on safety and effectiveness and the test results do not show any kind of risk potential for the user and/or the patient. Based on the test results and evaluation the modified devices are safe and effective for its intended use and are substantially equivalent to the named legally marketed devices. The modification does not alter the fundamental scientific technologies of the devices.

CONCLUSION

MAQUET Cardiopulmonary AG believes that the modified devices are substantially equivalent to the cleared MAQUET predicate devices regarding intended use of the devices, the indications for use, and the fundamental technology of the devices. Based on the risk analysis, MAQUET has conducted the appropriate design and verification and validation activities to demonstrate that the design outputs meet the design input requirements. MAQUET has concluded that the proposed changes are substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Maquet Cardiopulmonary Ag
c/o Ms. Katrin Schwenkglenks
Regulatory Affairs Manager
Hechinger Strasse 38, Hirrlingen
Germany 72145

SEP 15 2011

Re: K112360

Trade/Device Name: QUADROX-i Microporous Membrane Oxygenators Series;
QUADROX-iD Diffusion Membrane Oxygenators Series;
QUADROX-iR and
HLS modules and PLEGIOX Cardioplegia Heat Exchanger

Regulatory Number: 21 CFR 870.4350

Regulation Name: Cardiopulmonary Bypass Oxygenator

Regulatory Class: II (two)

Product Code: DTZ and DTM, DTR, KFM

Dated: August 12, 2011

Received: August 17, 2011

Dear Ms. Schwenkglenks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

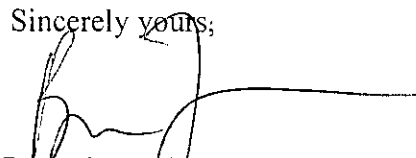
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours;

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', with a long horizontal line extending to the right.

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112360

Device Name: QUADROX-i Adult Microporous Membrane Oxygenator with and without integrated Arterial Filter

Indications for Use:

The membrane oxygenator Quadrox-i Adult is intended for the use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. Within the specified flow rate range, the device oxygenates the blood, eliminates carbon dioxide and regulates blood temperature. The Quadrox-i Adult (HMO 71000) version with integrated arterial filter also filters out air bubbles and particles larger than 40 μm . The device's utilization period is limited to six hours.

Responsibility for deciding whether to use an oxygenator rests solely with the attending physician

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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OF NEEDED)

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Indications for Use

510(k) Number (if known): K112360

Device Name: QUADROX-i Small Adult Microporous Membrane Oxygenator with and without integrated Arterial Filter

Indications for Use:

The membrane oxygenator QUADROX-i Small Adult is intended for the use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. The blood flow rate is defined from 0.5 – 5 L/min. Within the specified flow rate range, the device oxygenates the blood, eliminates carbon dioxide and regulates blood temperature. The QUADROX-i Small Adult (HMO 51000) version with integrated arterial filter also filters out air bubbles and particles larger than 40 µm. The device's utilization period is limited to six hours.

Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known): K112360

Device Name: QUADROX-i Pediatric Microporous Membrane Oxygenator
with and without integrated Arterial Filter

Indications for Use:

The membrane oxygenator QUADROX-i Pediatric is intended for use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. It is designed for a blood flow rate of 0.2 – 2.8 l/min and is intended for the treatment of pediatric patients. Within the specified flow rate range, the device oxygenates the blood, removes carbon dioxide and regulates the blood temperature.

The QUADROX-i Pediatric (HMO 31000) model with integrated arterial filter also filters air bubbles and particles larger than 33 µm.

The utilization period of this device is restricted to six hours.

Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known): K112360

Device Name: QUADROX-i Neonatal Microporous Membrane Oxygenator
with and without integrated Arterial Filter

Indications for Use:

The membrane oxygenator QUADROX-i Neonatal is intended for use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. It is designed for a blood flow rate of 0.2 – 1.5 l/min and is intended for the treatment of pediatric patients. Within the specified flow rate range, the device oxygenates the blood, removes carbon dioxide and regulates the blood temperature.

The QUADROX-i Neonatal (HMO 11000) model with integrated arterial filter also filters air bubbles and particles larger than 33 µm.

The utilization period of this device is restricted to six hours.

Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known): K112360

Device Name: QUADROX-iD Adult Diffusion Membrane Oxygenator

Indications-for-Use:

The QUADROX-iD Adult Diffusion Membrane Oxygenator is intended for use in an extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. Within the specified flow rate range, the device oxygenates the blood, removes carbon dioxide from the blood and regulates the blood temperature. The application duration is limited to 6 hours.

Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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(Posted November 13, 2003)

Indications for Use

510(k) Number (if known): K112360

Device Name: **QUADROX-iD Pediatric Diffusion Membrane Oxygenator**

Indications for Use:

The Diffusion Membrane Oxygenator QUADROX-iD Pediatric is intended for use in an extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. The oxygenator is designed for a blood flow rate of 0.2 – 2.8 l/min and is intended for the treatment of pediatric patients. Within the specified flow rate range, the device oxygenates the blood, removes carbon dioxide and regulates the blood temperature.

The utilization period for this device is restricted to six hours.

Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known): K112360

Device Name: **QUADROX-iR and HLS-modules as part of CARDIOHELP System**

Indications for Use:

The CARDIOHELP System is a blood oxygenation and carbon dioxide removal system used to pump blood through the extracorporeal bypass circuit for circulatory and/or pulmonary support during procedures requiring cardiopulmonary bypass (for periods up to six hours). It is also intended to provide circulatory and/or pulmonary support during procedures not requiring cardiopulmonary bypass (for periods up to six hours).

The CARDIOHELP System in configuration with the HLS/HIT Set Advanced is intended to be used within the hospital environment and outside the hospital environment (for periods up to six hours), e.g. for intra- and inter-hospital transport.

The CARDIOHELP System in configuration with the QUADROX-iR is intended to be used in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery (for periods for up to six hours).

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known): K112360

Device Name: **PLEGIOX Cardioplegia Heat Exchanger**

Indications for Use:

The PLEGIOX Heat Exchanger is used to set and maintain the temperature (for given flow rates and within the given temperature range) of blood cardioplegic and crystalloid cardioplegic solutions during extracorporeal circulation.

The product is designed for single use only, for an application period of no longer than 6 hours.

Prescription Use X

(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use

(21 CFR 801 Subpart C)

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(Division Sign-Off)

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